UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

CHELSEY STEPHENS, individually and on behalf of all others similarly situated, Plaintiff, v. LABORATORY CORPORATION OF AMERICA HOLDINGS, Defendant.	Case No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Chelsey Stephens ("Plaintiff" or "Ms. Stephens") brings this action on behalf of herself and all others similarly situated against Defendant Laboratory Corporation of America Holdings ("Labcorp" or "Defendant"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based upon personal knowledge.

NATURE OF THE ACTION

1. This is a putative class action lawsuit on behalf of purchasers of Labcorp's MateriniT Genome noninvasive prenatal screening test ("MateriniT" or "the Test"). Defendant markets and sells the Test by stating that it can reliability detect chromosomal abnormalities: "Noninvasive prenatal screening (NIPS/NIPT) tests can screen for trisomy 21 (Down syndrome) and other chromosomal abnormalities—as well as the sex of your baby—as early as nine weeks into your pregnancy, and with a high degree of accuracy."[1]

[1] NONINVASIVE PRENATAL SCREENING, https://womenshealth.labcorp.com/patients/pregnancy/noninvasive-prenatal-screening#.

2. However, although Non-Invasive Prenatal Testing ("NIPT") is generally effective at screening for Down syndrome, NIPT tests are largely unreliable to test for numerous other genetic conditions. For instance, a recent *New York Times* investigation found NIPT tests like Defendant's generate a high number of false positives and have a low positive predictive value for conditions like DiGeorge Syndrome, 1p36 deletion, Cri-du-chat syndrome, Wolf Hirschhorn syndrome, Prader-Willi and Angelman syndrome, Trisomy 13 (Patau syndrome) and Monosomy X (Turner syndrome).[2] Other studies have confirmed the unreliability of NIPT testing for these various conditions. Thus, the Test is worth far less than its market price.

3. Prenatal testing in recent years has moved towards non-invasive methods to determine the fetal risk for genetic disorders, including NIPT.[3]

4. NIPT analyzes DNA fragments from the blood of a pregnant woman to estimate the risk that the fetus will be born with certain genetic abnormalities, including chromosomal disorders like Trisomy 21 (Down syndrome) and Trisomy 18 (Edwards syndrome), and other, more rare disorders, like Trisomy 13 (Patau syndrome), Monosomy X (Turner syndrome) Prader-Willi, and Angelman Syndrome.

5. NIPT is incredibly popular. However, many of these tests are often unreliable, giving pregnant women false positive results for genetic conditions that their fetuses do not actually have. In addition, as a result of these false results, expecting mothers are often unnecessarily subjected to further diagnostic testing, genetic counseling, and even erroneous termination of a viable pregnancy.

[2] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html.

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545823/.

6. These problems extend to Defendant's Test, the MaterniT Genome, and encompass a number of conditions that MaterniT Genome tests for, such as Monosomy X, Trisomy 13, and various microdeletions.[4]

7. Despite the unreliability of the Test, Defendant falsely advertises the Test as having a "high degree of accuracy"[5] and fails to adequately give notice of the lack of reliability of the Test.

8. Plaintiff and Class Members purchased the Test designed, marketed, manufactured, distributed, and sold by Defendant as reliable. Plaintiff and Class Members would not have purchased Defendant's Test—or, at a minimum, would have paid significantly less for the Test—had they known the Tests were unreliable to test for numerous conditions. Plaintiff and Class Members thus suffered monetary damages as a result of Defendant's deceptive and false representations.

PARTIES

I. Plaintiff Chelsey Stephens

9. Plaintiff Chelsey Stephens is a resident of Brooklyn, New York, and has intent to remain there, and is therefore a citizen of New York. In or about January 2023, while in Brooklyn, Ms. Stephens underwent genetic testing, using LabCorp's MaterniT Genome test. Specifically, Ms. Stephens tested for the following conditions: (i) Autosomal Aneuploidies (Trisomies 13, 18, and 21), (ii) Sex Chromosome Aneuplodies (the sex of her child, in addition

[4] Microdeletions encompass a wide variety of conditions and occur when "small pieces of chromosome" are missing. "They can have a wide range of symptoms, including intellectual disability, heart defects, a shortened life span or a high infant mortality rate." https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html.

[5] https://womenshealth.labcorp.com/patients/pregnancy/noninvasive-prenatal-screening#:~:text=Noninvasive%20prenatal%20screening%20(NIPS%2FNIPT,a%20high%20degree%20of%20accuracy.

to Turner syndrome, Jacobs syndrome, Klinefelter syndrome, and Triple X syndrome), (iii) Genome-Wide Copy Number variants, and (iv) Select Microdeletions. Prior to paying for the MateriniT NIPT test, Ms. Stephens encountered materials prepared by Defendant.

10. On February 3, 2023, Ms. Stephens received her test results. The results showed "Positive" for Monosomy X (Turner syndrome), a chromosomal disorder that can lead to a variety of medical and developmental problems requiring lifelong medical care, including infertility, heart defects, diabetes, low thyroid hormone, and a high risk that the child would not be born alive. Neither prior to undergoing the test nor on the test results themselves did Defendant disclose to Ms. Stephens that the Test was unreliable to test for Monosomy X, among various other conditions. Specifically, Defendant failed to note that NIPT testing for Monosomy X has a positive predictive value ("PPV") of 27% (meaning a positive result is only 27% likely to be correct) and a 73% false positive rate ("FPR"). On the contrary, the test results noted in that "the results of these tests are highly reliable."

11. Due to this finding, Ms. Stephens suffered emotional distress, stress, and anxiety, and felt immense pressure to terminate her pregnancy. Ms. Stephens also underwent amniocentesis testing, which she paid for out of pocket. The results of the amniocentesis showed that her baby did not have Monosomy X. This was particularly stressful to Ms. Stephens because the amniocentesis had a risk of causing her to miscarry.

12. Nowhere in Defendant's testing brochure, on its website, or in its marketing materials did Defendant disclose the low PPV and high false positive rates associated with many of the conditions for which MateriniT tests, including Monosomy X. Nor did Defendant disclose in any marketing materials that, as a result of these deficiencies and others alleged herein, the

MaterniT test could not accurately or reliably determine whether Ms. Stephen's baby had or was at risk of having a genetic abnormality.

13. Had Defendant disclosed that the MaterniT NIPT was neither accurate nor reliable to test for the majority of genetic conditions it purported to identify, including Monosomy X, Ms. Stephens would not have purchased the Test, or would have paid significantly less for it. Accordingly, Ms. Stephens was injured by virtue of the price premium she paid as a result of Defendant's failure to disclose the unreliability of the MaterniT test.

II. Defendant

14. Defendant Labcorp is a corporation organized and existing under the law of the State of Delaware with its principal place of business in Burlington, North Carolina. Defendant markets, distributes, and sells its MaterniT test throughout the United States and the State of New York.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000, exclusive of interest and costs, there are over 100 members of the putative class, and Plaintiff, as well as most members of the proposed class, are citizens of states different from Defendant.

16. This Court has personal jurisdiction over Defendant because it conducts substantial business within New York, such that Defendant has significant, continuous, and pervasive contacts within the State of New York and because a substantial portion of the events that gave rise to this cause of action occurred here.

17. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant transacts significant business within this District and because Plaintiff paid for and used the MateriniT Genome in this District.

FACTUAL ALLEGATIONS

I. Defendant Represents MateriniT Is Reliable To Test For Various Genetic Conditions

18. Prenatal testing is used to assess a pregnant patient's risk of carrying a child with chromosomal disorders that can affect the baby's health. When prenatal genetic testing provides accurate results, it in turn provides to pregnant patients valuable information about the health of their unborn child. The genetic conditions these tests are directed toward finding can make a pregnancy non-viable or have serious impacts on the health of a surviving newborn, such as structural anomalies, intellectual disabilities, and a shortened lifespan.

19. The discovery of fetal DNA in maternal blood has led to changes in prenatal screening. Following this discovery, many companies began working on blood tests, otherwise known as NIPT, aimed at detecting chromosomal abnormalities without the invasive and risky nature of amniocentesis and chorionic villus sampling ("CVS").[6]

20. Although historically only offered to patients considered to be high risk because of their age or personal or family history, prenatal screening has expanded significantly in the last decade. NIPT was developed and grew until the American College of Obstetricians and Gynecologists ("ACOG") changed its guidance in 2020 to recommend that all pregnant patients "be offered both screening and diagnostic testing options."[7] The ACOG's guidance is that "[t]esting for chromosomal abnormalities should be an informed patient choice based on

[6] https://blog.seracare.com/ngs/evolution-of-non-invasive-prenatal-testing-nipt-testing.

[7] https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test.

provisions of adequate and accurate information, and the patient's clinical context, accessible health care resources, values, interest, and goals."[8]

21. The market for prenatal testing was recently estimated to range from $600 million and is growing rapidly, with the number of women taking these tests expected to double by 2025.[9]

22. In the early 2010s, Sequenom Laboratories developed what it called the MateriT21 NIPT. The test became highly successful. Labcorp purchased Sequenom Laboratories and began offering the MateriT test as a noninvasive blood screen for pregnant women to find out if their babies have an increased risk of chromosomal conditions like Patau Syndrome (Trisomy 13), Down Syndrome (Trisomy 21) and Edwards Syndrome (Trisomy 18). A pregnant patient whose child has one of these conditions faces serious questions about risks in continuing the pregnancy, the viability of the pregnancy, and the prognosis and quality of life for any surviving newborn.

23. Defendant's website states, ""Noninvasive prenatal screening (NIPS/NIPT) tests can screen for trisomy 21 (Down syndrome) and other chromosomal abnormalities—as well as the sex of your baby—as early as nine weeks into your pregnancy, and with a high degree of accuracy."[10]

[8] *Id.*

[9] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html.

[10] https://womenshealth.labcorp.com/patients/pregnancy/noninvasive-prenatal-screening.

24. By default, the MaterniT Genome tests for any trisomy or monosomy, sex chromosome abnormalities, and partial chromosome abnormalities.[11]

MaterniT GENOME reports on:	
Any trisomy or monosomy	• Trisomy: an extra copy of a chromosome is present (3 instead of 2) • Monosomy: a missing copy of a chromosome (1 instead of 2)
Sex chromosome abnormalities	• An atypical number of X and/or Y chromosomes beyond typical female (XX) or male (XY) complement
Partial chromosome abnormalities	• Missing or extra parts of the chromosome

25. Defendant's brochure and website makes uniform representations as to the MaterniT Test generally, other than describing what each condition is. That is, regardless of whether a woman chooses the default MaterniT GENOME panel or adds on testing for additional disorders, she will see the same, or substantially similar, representations of reliability, and these representations do not distinguish between a test for Down Syndrome, a test for Monosomy X, or a test for microdeletions.

26. In its Brochure and on its website, Defendant represents that the Test provides "crucial insights as early as nine weeks as early as nine weeks into your pregnancy"[12] which can mean better care for you and your baby, before and after delivery."[13] The Brochure also states,

[11] https://womenshealth.labcorp.com/sites/default/files/2023-01/DX_BRO_L17294-1122-6-2.pdf.

[12] https://fenwayhealth.org/wp-content/uploads/MaterniT-Advanced-Screening-Patient-Brochure.pdf.

[13] *Id.*

"MaterniT GENOME ensures screening results are communicated clearly—as positives or negatives."[14]

27. Defendant's website further states "MaterniT GENOME can tell you if you screen positive or negative for trisomies 21 (Down syndrome), 18 (Edwards syndrome), and 13 (Patau syndrome), and if you're having a boy or a girl. But it can also find other chromosomal changes that may go undiagnosed at birth."[15]

28. Again, Defendant makes these representations of reliability and trustworthiness throughout its marketing and advertising campaign. The brochure and website do not distinguish among tests for the different possible genetic anomalies with respect to accuracy and reliability.

29. Thus, as to each condition that MaterniT can test for, Defendant represents that MaterniT can reliably and accurately test for that condition, such as Trisomy 13, 18, 21, Monosomy X, various sex chromosome disorders, and microdeletions. Moreover, Defendant represents to consumers that they should trust the results they receive for their test because the MaterniT Test is of a high degree of reliability. These representations are uniform and do not differ or distinguish between testing for each condition.

30. Tests like MaterniT Genome are costly. The average cost for NIPT tests in the United States is $279 out-of-pocket.[16]

II. MaterniT Is Unreliable To Test For A Variety of Genetic Conditions, Including Monsomy X, Trisomy 13, and Microdeletions.

31. While MaterniT may work well for Trisomy 18 and 21, the MaterniT Genome

[14] *Id.*

[15] *Id.*

[16] http://www.motherofmicrobes.com/the-nipt-test-costs-less-than-you-think-but-beware-of-insurance-surprises/

Test is alarmingly unreliable for various other conditions.

32. A recent *New York Times* investigation found that despite NIPT tests—including Labcorp's— being advertised as "trustworthy," "highly accurate," "reliable," and providing "peace of mind" for patients, the tests have a high FPR and low PPV for conditions like DiGeorge Syndrome, 1p36 deletion, Cri-du-chat syndrome, Wolf Hirschhorn syndrome, Prader-Willi and Angelman syndrome, Trisomy 13 (Patau syndrome) and Monosomy X (Turner syndrome).

33. Studies largely confirm the inability of NIPT testing like Defendant's to reliably test for numerous conditions. For instance, a 2017 study[17] examined "the the positive predictive value and false-positive rates for different chromosomal abnormalities identified by cell-free fetal DNA screening [*i.e.*, NIPT testing]."[18] The study found that (i) the FPR for Trisomy 13 was 55% and the PPV was 45%; (ii) the FPR for Monosomy X was 73% and the PPV was 27%; and (iii) the FPR for XXX syndrome was 55% and the PPV was 45%[19]:

[17] Andrea K. Petersen et al., *Positive Predictive Value Estimates for Cell-Free Noninvasive Prenatal Screening From Data of a Large Referral Genetic Diagnostic Laboratory*, 691 AM. J. OBSTETRICS & GYNECOLOGY 1 (2017), https://www.sciencedirect.com/science/article/pii/S0002937817311870.

[18] *Id.* at 1.

[19] *Id.* at 3.

TABLE 1
Cases with cffDNA screening results positive for aneuploidy

cffDNA screening result	n	TP (n)	PPV	FPR
Trisomy 13	76	34	45%	55%
Trisomy 18	106	82	77%	23%
Trisomy 21	268	228	85%	15%
Monosomy X	89	24	27%	73%
XXY	20	17	85%	15%
XXX	11	5	45%	55%
XYY	4	4	—	—
Monosomy 13	3	0	—	—
Monosomy 18	2	0	—	—
Trisomy 7	1	0	—	—
Trisomy 9	2	0	—	—
Trisomy 14	1	0	—	—
Trisomy 16	3	1	—	—

cffDNA, cell-free fetal DNA; *FPR*, false-positive rate; *PPV*, positive predictive value; *TP*, true positive.
Petersen et al. Positive predictive value estimates for noninvasive prenatal screening. Am J Obstet Gynecol 2017.

34. In other words, the study found a positive result for Monosomy X was likely to be wrong over 70% of the time, a positive result for Trisomy 13 or XXX syndrome was likely to be wrong more than half the time.

35. The study found NIPT testing for microdeletions to be equally as unreliable, if not worse: "[t]he combined PPV for all microdeletion-positive cffDNA screen cases in [the study's] data set was 13%, while the PPV for the most frequent microdeletion in [the study's] data set (22q11.2/DiGeorge syndrome deletion, n = 28) was 21%."[20]

[20] *Id.* at 3-4.

36. Another study from 2017 found the PPV for Monosomy X (Turner syndrome) was 29.41% and noted "the accuracy needs to be improved particularly for Turner syndrome."[21] Yet another study from 2019 found the average PPV for Monosomy X to be 26.1%.[22] And a third study found the PPV for Monosomy X was only 23%-26%, while the PPV for Trisomy 13 was only 45%.[23] Similarly, for Trisomy 13, a 2015 study found the FPV for Trisomy 13 was 56% while the PPV was only 44%.[24] In addition, a 2018 study found the PPV for various microdeletions was as low as 6.6%.[25]

37. The long and short of these various studies is that NIPT testing like MarterniT cannot reliably determine whether an unborn child has any number of the genetic conditions the Test tests for, such as Monosomy X, Trisomy 13, and various microdeletions. If a woman receives a positive result, it is at best close to a coin flip whether that result is correct (*i.e.*, for Trisomy 13, where the PPV is approximately 45%). And at worst, the positive result is significantly more likely to be wrong for Monosomy X and the various microdeletions. This dramatically reduces the value of a test like MarterniT that markets its ability to "screen for more than Down Syndrome."[26]

---

[21] Bin Zhang et al. *Noninvasive Prenatal Screening for Fetal Common Sex Chromosome Aneuploidies from Maternal Blood*, 45 J. INT'L MED. RSCH. 621, 627-28 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5536640/pdf/10.1177_0300060517695008.pdf

[22] DIANA W. BIANCHI, TURNER SYNDROME: NEW INSIGHTS FROM PRENATAL GENOMICS AND TRANSCRIPTOMICS 10 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10110351/pdf/nihms-1888280.pdf.

[23] M. Katharine Rudd, et al., *Monosomy X Rescue Explains Discordant NIPT Results and Leads to Uniparental Isodisomy*, 38 PRENATAL DIAGNOSIS 920, 920 (2018), https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/pd.5349.

[24] Jia-Chi Wang, et. al., *Discordant Noninvasive Prenatal Testing And Cytogenetic Results: A Study Of 109 Consecutive Cases*, 17 GENETICS IN MEDICINE 234, 235 (2015).

[25] S. Schwartz et al., *Clinical Experience of Laboratory Follow-Up with Noninvasive Prenatal Testing Using Cell-Free DNA and Positive Microdeletion Results in 349 Cases*, 38 PRENATAL DIAGNOSIS 210, 212 (2018), https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1002/pd.5217.

[26] https://womenshealth.labcorp.com/patients/pregnancy/maternit-genome.

38. The market for NIPT is not heavily regulated. "There are few restrictions on what test makers can offer. The FDA often requires evaluations of how frequently other consequential medical tests are right and whether shortfalls are clearly explained to patients and doctors. But the FDA does not regulate this type of test."[27]

39. As a result, consumers are easily confused by the marketing of companies like Labcorp. According to the *New York Times*, a former director of the FDA office that oversees many medical tests "reviewed marketing materials from three testing companies and described them as 'problematic'" and "misleading." As the official put it, "These numbers are meaningless."[28]

40. In addition, in early 2022, a report by the Hastings Center "analyze[d] all available English-language consumer-directed NIPT brochures," and concluded that the communications "substantiate concerns about bias and inaccuracy in the promotion of these screening tests."[29]

41. The Hastings Report "raise[d] concerns about the commercial marketing of NIPT, noting that a company's interest in promoting its tests could influence the messages it conveys to consumers." Specifically, the report described many of the marketing materials as "incomplete, unsubstantiated, inaccurate, misleading, or emotive," which compromises "the consumer's ability to make informed choices."[30]

---

[27] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html.

[28] *Id.*

[29] Kelly Holloway, et al., *The Market in Noninvasive Prenatal Tests and the Message to Consumers: Exploring Responsibility*, 52 HASTINGS CENTER REPORT 1, 3 (2022), https://s3.documentcloud.org/documents/21411047/simms-ev-feb-9.pdf ("Hastings Report").

[30] *Id.* at 1.

42. The Hastings Report went on to state that "[t]he potential for bias in industry-developed information about NIPT, in addition to the lack of regulatory oversight for this type of product, raises questions about clinical communication and appropriate adoption."[31] The *New York Times* noted "[p]oor-quality information poses the potential for harm from increased shock, distress, and confusion upon receipt of a high-chance result and may even lead to termination of an unaffected fetus if the possibility of a false-positive result is not clearly communicated."[32]

43. Recognizing these concerns, in April 2022, the FDA issued a safety communication about NIPT tests, warning that "Genetic Non-Invasive Prenatal Screening Tests May Have False Results."[33] The statement, directed to "patients and health care providers," emphasizes that "[w]hile health care providers widely use NIPS tests, none have yet been authorized, cleared, or approved by the FDA" and "[t]he accuracy and performance of NIPS tests have not been evaluated by the FDA and these tests can give false results."[34]

44. The FDA safety communication noted that the FDA is aware of reports that "pregnant people have ended pregnancies based only on the results of NIPS tests," and stated that "[g]iven the increased use of these tests and concerns raised in recent media reports, the FDA is providing this information to educate patients and health care providers and to help reduce the inappropriate use of NIPS tests."[35] It stated that patients and health care providers

---

[31] *Id.* at 2.

[32] https://www.medpagetoday.com/special-reports/exclusives/97654

[33] https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication.

[34] *Id.*

[35] *Id.*

alike "should be aware of the risks and limitations of using these screening tests," and made specific recommendations for patients and for health care providers to become better informed.

45. Finally, the FDA safety communication noted "the risks related to the use of genetic prenatal screening and the potential harm if NIPS test results are not used and interpreted appropriately" and "encourages test developers to provide accurate, clear, and complete information about the performance of their tests, how they should be used, and what the results may or may not mean."[36]

46. Labcorp's aforementioned representations support the concerns about marketing of NIPT tests. Not only does Labcorp represent that the Test can reliably test for various genetic conditions, but Labcorp fails to disclose that NIPT testing such as MateriniT Genome is unreliable to test for a number of genetic conditions, such as, but not limited to, Monsomy X, Trisomy 13, and various microdeletions. Labcorp does not disclose the high FPV and low PPV for these conditions using its Test.

47. The outcomes of these false positive results can be harmful to the mother and fetus. In addition to the anguish for the potentially compromised health of their child, parents with positive test results also must contend with the prospect of expansive and stressful doctor's appointments with high-risk pregnancy specialists, often incurring increased costs for these extra visits and increased testing.[37] For example, following a false positive result, low-risk pregnant women are forced to undergo additional, and very invasive testing, including amniocentesis and

[36] *Id.*

[37] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html ("Patients who receive a positive result are supposed to pursue follow-up testing, which often requires a drawing of amniotic fluid or a sample of placental tissue. Those tests can cost thousands of dollars, come with a small risk of miscarriage and can't be performed until later in pregnancy—in some states, past the point where abortions are legal.").

CVS. During an amniocentesis, a needle is used to remove amniotic fluid from the uterus for testing. Similarly, during a CVS procedure, a catheter or needle is used to biopsy placental cells that are derived from the same fertilized egg as the fetus. Both procedures include an increased risk of miscarriage.[38]

48. Many women also have abortions after obtaining positive results from NIPT screens, even though those results may very well be inaccurate. For example, a 2014 study found that six percent of patients who screened positive obtained an abortion without getting another test to confirm the results.[39]

49. Moreover, one United Kingdom study in 2017, found that 63% of U.K. women with high-risk NIPT results go to terminate their pregnancies.[40]

50. Consumers are therefore paying hundreds of dollars for testing that is highly inaccurate, untrustworthy, and causing needless and dangerous risk to the mother and child.

III. Defendant's Misrepresentations And Omissions Are Actionable

51. Plaintiff and Class Members were injured because they paid a premium for the Test or otherwise paid more for the Test based on Defendant's misrepresentations that the Test was reliable and Defendant's failure to disclose that the Test was largely unreliable and inaccurate to test for a number of conditions, like Trisomy 13, Turner Syndrome, and microdeletions.

---

[38] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

[39] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html

[40] M. Hill et al., "Has Noninvasive Prenatal Testing Impacted Termination of Pregnancy and Live Birth Rates of Infants with Down Syndrome?," *Prenatal Diagnosis* 37, no. 13 (2017): 1281-90.

52. Plaintiff and Class Members bargained for a Test that would provide them with reliable results but were deprived of the basis of their bargain when Defendant sold them a largely unreliable test while failing to disclose the Test's unreliability.

53. Plaintiff satisfies the requirements of Rule 9(b) by alleging the following facts with particularity:

WHO: Defendant made material misrepresentations and/or omissions of fact about the Test through their brochure and website that the Test was reliable and trustworthy. Defendant made these representations as to the Test generally and each condition it tests for and did not distinguish between the reliability of the tests for certain conditions as opposed to others (*e.g.,* Down Syndrome vs. Monosomy X and microdeletions).

WHAT: Defendant's conduct here was, and continues to be, fraudulent because it fails to disclose the Test is unreliable to test for a variety of genetic conditions like Monosomy X, Trisomy 13, and microdeletions, or otherwise misrepresents that the Test was reliable to reliably test for the same conditions. Thus, Defendant's conduct deceived Plaintiff and Class Members into believing that the Test was reliable. Defendant knew or should have known that this information is material to reasonable consumers, including Plaintiff, in making their purchasing decisions, yet Defendant continued to pervasively market the Tests in this manner.

WHEN: Defendant made material misrepresentations and/or omissions prior to and at the time Plaintiff and Class Members purchased the Test, despite the fact that Defendant knew or should have known that the testing was highly inaccurate. Defendant made material misrepresentations and/or failed to disclose material facts regarding the unreliability of the Test.

HOW: Defendant made material misrepresentations and/or failed to disclose material facts regarding the inaccuracy of the Test.

WHY: Defendant made the material misrepresentations and/or omissions detailed herein for the express purpose of inducing Plaintiff, Class Members, and all reasonable consumers to purchase and/or pay for the Test, the effect of which was that Defendant profited by selling the Test to thousands of consumers.

INJURY: Plaintiff and Class Members paid a premium, or otherwise paid more for the Test when they otherwise would not have, but for Defendant's misrepresentations and/or omissions.

54. It does not matter whether or not Plaintiff and Class Members received a false positive result. Plaintiff and the Class's injury is economic: they were charged more than they should have been for a Test that was unreliable, but which Defendant represented was reliable. Plaintiff and the Class would not have purchased the Test or would have paid significantly less had they known the Test was inaccurate and unreliable to test for a number of conditions. In other words, Plaintiff and Class Members were injured at the time of purchase, not at the time they received their results, because an unreliable test like MateriT was worth less to Plaintiff and Class Members than a reliable one.

55. As a result of Defendant's misrepresentations and omissions, Plaintiff brings this action on behalf of herself and the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of implied warranty; (iii) unjust enrichment; (iv) fraud; (v) violation of the Magnuson-Moss Warranty Act ("MMWA"), 15 U.S.C. §§ 2301, *et seq.*; (vi) violation of New York General Business Law ("GBL") § 349; and (vii) Violation of New York General Business Law ("GBL") § 350.

CLASS ALLEGATIONS

56. Plaintiff seeks to represent a class defined as all persons in the United States who purchased a MateriT Genome Test (the "Nationwide Class").

57. Plaintiff also seeks to represent a class defined as all persons who reside in the State of New York who purchased a MateriT Genome Test (the "New York Subclass").

58. The Nationwide Class and New York Subclass shall collectively be referred to as the "Class."

59. Specially excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children,

corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

60. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint.

61. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendant and may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

62. **Existence and Predominance of Common Issues of Law and Fact.** Common questions of law and fact exists as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Test, manufactured, distributed, and sold by Defendant, was unfit for use as a screening test, thereby breaching express and implied warranties made by Defendant by making the Test unfit for its intended purpose;

(b) whether Defendant knew or should have known that the Test was unreliable prior to selling the Test, thereby constituting fraud and/or fraudulent omission;

(c) whether Defendant is liable to Plaintiff and the Class for unjust enrichment;

(d) whether Plaintiff and the Class have sustained monetary loss and the proper measure of that loss;

(e) whether Plaintiff and the class are entitled to restitution and disgorgement for Defendants; and

(f) Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Test are deceptive.

63. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class in that Defendant mass marketed and sold unreliable Tests to consumers throughout the United States. This unreliability was present in all the Tests manufactured, distributed, and sold by Defendants. Therefore, Defendant breached its express and implied warranties to Plaintiff and the Class members by manufacturing, distributing, and selling the unreliable Test. Plaintiff's claims are typical in that she was uniformly harmed in purchasing and using the unreliable Test. Plaintiff's claims are further typical in that Defendant deceived Plaintiff in the very same manner as it deceived each member of the Class. Further, there are no defenses available to Defendant that are unique to Plaintiff.

64. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class.

65. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members are relatively small compared to the burden and expenses of

individual litigation of their claims against Defendants. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual manages difficulties under the circumstances.

66. In the alternative, the Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual members that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Class as a whole, thereby making appropriate final declaratory relief with respect to the members of the Class as a whole.

COUNT I
BREACH OF EXPRESS WARRANTY
(On Behalf Of The Class)

67. Plaintiff incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

68. Plaintiff brings this claim individually and on behalf of the proposed Class against

Defendant.

69. This count is brought under the laws of the State of New York.

70. In connection with the sales of the Test, Defendant, as designer, manufacturer, marketer, distributor, and/or seller issues written warranties by representing that the Test was "highly accurate."

71. However, the Test did not conform to the above-reference representations because the Test is unreliable, returning a large number of false positives for conditions like Trisomy 13, microdeletions and monosomy X.

72. Plaintiff and Class Members were injured as a direct result and proximate result of Defendant's breaches because they would not have purchased the Tests if they had known that the Tests did not work as Defendant warranted.

73. On May 23, 2023, prior to filing this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breaches an express warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1.**

COUNT II
Breach of Implied Warranty
(On Behalf of The Class)

74. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

75. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

76. This count is brought under the laws of the State of New York.

77. Defendant, as designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the Test was suited for use to detect chromosomal abnormalities with a high degree of accuracy. Defendant breached the warranty implied in the contract for the sale of the Test because the Test could not "pass without objection int eh trade under the contract description," the Test was not "of fair average quality within the description," the Test was not "adequately contained, packaged, and labeled as the agreement may require," and the Test did not "conform to the promise or affirmations of fact made on the container or label." *See* U.C.C. §2-314(2) (listing requirements for merchantability). As a result, Plaintiff and the Class Members did not receive the goods as implied warranted by Defendant to be merchantable.

78. Plaintiff and the Class Members purchased the Tests in reliance upon Defendant's skill and judgment in properly packaging and labeling the Tests.

79. The Test was not altered by Plaintiff and Class Members.

80. The Test was not fit for its intended purpose when they it left the exclusive control of Defendant.

81. Defendant knew that the Test would be purchased and used without additional testing by Plaintiff and Class Members.

82. The Test was defectively designed and unfit for their intended purpose, and Plaintiff and Class Members did not receive the Test as warranted.

83. Plaintiff and member of the Class were injured as a direct and proximate result of Defendant's breach because (i) they would not have purchased the Test if they had known that the Test was unreliable, highly inaccurate, not dependable, and therefore unsuitable for its stated and advertised purpose of detecting chromosomal abnormalities with a high degree of accuracy,

and (ii) they overpaid for the Test on account of its misrepresentations that it was capable of detecting chromosomal abnormalities with a high degree of reliability.

84. On May 23, 2023, prior to the filing of this action, Defendant was served with a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of this letter is attached hereto as **Exhibit 1**.

COUNT III
Unjust Enrichment
(On Behalf Of The Class)

85. Plaintiff hereby incorporated by reference the allegations contained in the preceding paragraphs of the complaint.

86. Plaintiff brings this claim individually and on behalf of the members of the proposed nationwide Class against Defendant.

87. This count is brought under the laws of the State of New York.

88. Plaintiff and the Class conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective Test.

89. Defendant voluntarily accepted and retained this benefit.

90. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for testing devices unfit for the purpose in which they were sold, it would be unjust and inequitable for the Defendant to retain it without paying the value thereof.

COUNT IV
Fraud
(On Behalf Of The Class)

91. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

92. Plaintiff brings this claim individually and on behalf of the members of the proposed Class against Defendant.

93. This count is brought under the laws of the State of New York.

94. As discussed above, Defendant provided Plaintiff and Class Members with materially false or misleading information about the Test manufactured, distributed, and sold by Defendant. Specifically, Defendant had knowledge of the fact that Test was unreliable, often resulting in false positive results. Defendant nevertheless actively represented to consumers that the Test was reliable, accurate, and trustworthy, or otherwise failed to disclose that the Test was unreliable to test for a variety of genetic conditions.

95. The misrepresentations and omissions of material fact made by Defendant, upon which Plaintiff and Class Members reasonably and justifiably relied, were intended to induce, and actually induced, Plaintiff and Class Members to purchase the unreliable Labcorp Test.

96. The fraudulent actions of Defendant caused damages to Plaintiff and Class Members, who are entitled to damages and other legal and equitable relief as a result.

97. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT V
Violation Of The Magnuson-Moss Warranty Act,
15 U.S.C. §§ 2301, *et seq.*
(On Behalf Of The Class)

98. Plaintiff incorporates by reference the allegations contained in the preceding

paragraphs of this complaint.

99. Plaintiff brings this claim individually and on behalf of the members of the of the proposed Class against Defendant.

100. The Product is a consumer product as defined in 15 U.S.C. § 2301(1).

101. Plaintiff and the Class are consumers as defined in 15 U.S.C. § 2301(3).

102. Defendant is a supplier and warrantor as defined in 15 U.S.C. § 2301(4) and (5).

103. In connection with the marketing and sale of the Tests, Defendant expressly and impliedly warranted that the Test was capable of producing "accurate," "reliable" and trustworthy results. However, the Test was not capable of producing those results as described in the allegations above.

104. By reason of Defendant's breach of warranties, Defendant violated the statutory rights due to Plaintiff and members of the Class pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.,* thereby damaging Plaintiff and the members of the Class.

105. Plaintiff and members of the Class were injured as a direct and proximate result of Defendant's breach because they would not have purchased the Test if they knew that the Test was not capable of reliably producing "accurate" and trustworthy results, and therefore Defendant's claims about the Test's accuracy and reliability were false and misleading.

COUNT VII
Violation of New York's Gen. Bus. Law § 349
(On Behalf of the New York Subclass)

106. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

107. Plaintiff brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendant.

108. By the acts and conduct alleged herein, Defendant committed unfair or deceptive acts and practices by making false representations regarding the Test.

109. The foregoing deceptive acts and practices were directed at consumers.

110. The foregoing deceptive acts and practices were misleading in a material way because they fundamentally misrepresent that the Test was capable of producing reliable and trustworthy results for a number of genetic conditions, or otherwise fail to disclose the Test is not capable of producing reliable and trustworthy results for a number of genetic conditions.

111. Plaintiff and members of the New York Subclass were injured as a result of Defendant's deceptive acts and practices because they would not have purchased the Test, or would have paid substantially less for it, but for Defendant's misrepresentations and omissions concerning the reliability of the Test.

112. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorney's fees.

COUNT VIII
Violation of New York's Gen. Bus. Law § 350
(On Behalf of the New York Subclass)

113. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

114. Plaintiffs bring this claim individually and on behalf of the members of the proposed Subclass against Defendant.

115. Based on the foregoing, Defendant engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of GBL § 350 by misrepresenting or failing to disclose the qualities and characteristics of the Test.

116. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.

117. These misrepresentations and omissions have resulted in consumer injury or harm to the public interest.

118. Defendant possessed the knowledge that the Test was not capable of producing reliable and trustworthy results.

119. Plaintiff and members of the New York Subclass were injured as a result of Defendant's false advertising because they would not have purchased the Test, or would have paid substantially less for it, but for Defendant's misrepresentations and omissions concerning the reliability of the Test.

120. On behalf of herself and other members of the New York Subclass, Plaintiff seeks to recover her actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all other similarly situated, seeks judgement against Defendants, as follows:

(a) For an order certifying the Nationwide Class and New York Subclass under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as representative of the Nationwide Class and New York Subclass, and naming Plaintiff's attorneys as Class Counsel to represent the Nationwide Class and New York Subclass;

(b) For an order declaring the Defendant's conduct violates the statutes referenced herein;

(c) For an order finding in favor of Plaintiff, the Nationwide Class and New York Subclass on all counts asserted herein;

(d) For compensatory, statutory, and punitive damages in amounts to

be determined by the Court and/or jury;

(e) For prejudgment interest on all amounts awarded;

(f) For an order of restitution and all other forms of equitable monetary relief; and

(g) For an order awarding Plaintiff, Nationwide Class and New York Subclass their reasonable attorneys' fees and expenses and costs of suit.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on any and all claims so triable.

Dated: June 9, 2023

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ Joshua D. Arisohn*
Joshua D. Arisohn

Joshua D. Arisohn
Max S. Roberts
Julian C. Diamond
1330 Avenue of the Americas, 32nd Floor
New York, NY 10019
Telephone: (646) 837-7150
Facsimile: (212) 989-9163
Email: jarisohn@bursor.com
mroberts@bursor.com
jdiamond@bursor.com

Attorneys for Plaintiff